JAN 1 6 2004

Product Performance and Substantial Equivalency
510k Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033344

Submitter: Consolidated Technologies
4401 Freidrich Lane
Building 1, Suite 100
Austin, TX 78744-1832
Phone: (512) 445-5100
Fax: (512) 445-5515

Contact: Candice Betz **Preparation date:** October 2nd, 2003

Product name (trade & common):

Proprietary: LIGAND PLUS CONTROL Level 1 – 3

Also sold as:

Consolidated Technologies will also sell this product as an unassayed OEM product, as well as an assayed OEM product. Individual customers will establish analyte assay criteria from the list of analytes provided. Consolidated Technologies will manufacture the product to the customer specifications (refer to Exhibit I). Customer specifications and Labeling criteria of OEM customers are maintained in the 510k file. Any regulatory compliance for labeling is the OEM Customers' responsibility.

Classification name:

Product code: DIF

CFR section: 21CFR 862.3280 Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Predicate device:

IMMUNOASSAY PLUS CONTROL Levels 1, 2 and 3 Consolidated Technologies, notification number K020237.

Product Performance and Substantial Equivalency
510(k) Summary (continued)

Device description:
LIGAND PLUS CONTROL is designed to monitor the performance of test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert.

Human origin components are added to a human serum based matrix. The product contains <0.1% sodium azide.

This product will be offered as an assayed or unassayed three level control.

Intended use:
LIGAND PLUS CONTROL is a lyophilized human serum based assayed quality control material intended to monitor the performance of serum immunoassay test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert.

Comparative analysis:
The table below provides a summary of the technological characteristics between LIGAND PLUS CONTROL and the predicate device.

Device Characteristic	**Proposed Device** LIGAND PLUS CONTROL	**Predicate Device** IMMUNOASSAY PLUS CONTROL
Intended use	Assayed or unassayed quality control for monitoring performance of routine chemistry test procedures.	Assayed or unassayed quality control for monitoring performance of routine chemistry test procedures.
Matrix	Processed Human Serum	Processed Human Serum
Form	Lyophilized	Lyophilized
Analytes	55 analytes of clinical significance	59 analytes of clinical significance
Levels	Three (3) Levels	Three (3) levels
Storage	2 °C to 8 °C	2 °C to 8 °C
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label.

Product Performance and Substantial Equivalency
510(k) Summary (continued)

Labeling/Packaging:

Consolidated Technologies is a manufacturer and a contract manufacturer of OEM products. The following will describe the potential ways that LIGAND PLUS CONTROL could be labeled.

Consolidated Technologies is a manufacture and will sell this product as LIGAND PLUS CONTROL. The package insert will list the analytes present in the control and the values obtained for those analytes on various test methods and/or instrumentation. The assay sheet included in this 510k is an example of potential methods used to assay the product. See Exhibit III thru Exhibit VI, for all labeling and package insert and example assay sheet.

LIGAND PLUS CONTROL Levels 1 – 3 will be packaged as follows:

5 X 5.0 mL Levels 1-3
Package Insert/assay sheet

Consolidated Technologies is a contract manufacturer. The expected values listed on the Product Requirement Document (product specification) for LIGAND PLUS CONTROL are target ranges developed for manufacturing purposes only (see Exhibit I). These expected values are based on the product having three distinct levels. As such, CTI will manufacture, at the request of a customer, either unassayed or assayed LIGAND PLUS CONTROL product.

If the customer requests an unassayed product, the expected manufacturing targets for the product will be presented for reference and a certificate of analysis will accompany the final product for completion. The certificate of analysis will list the actual values obtained for analytes present in the control (see Exhibit II for example).

If the customer requests an assayed control, the customer will determine the test methods, specific analytes (from submitted analyte list), and instrumentation. The value assignment data (assayed) are provided to the customer to develop their own package insert. Consolidated Technologies will provide a certificate of analysis that lists the actual values obtained for the analytes specified by the customer. See exhibit I for C of A.

The customer is responsible for labeling and/or package insert for finished device.

OEM product is offered to customers in the following configurations:

5ml fill in a 7ml amber glass vial	Unlabeled vials in labeled flats
Customer labeled vials in flats	Customer labeled vials in labeled kits

Conclusions:

The information provided in the pre-market notification demonstrates that LIGAND PLUS CONTROL is substantially equivalent to the predicate device, for which there is FDA clearance. This equivalence was demonstrated through comparison of intended uses and physical properties to a commercially available device. The information supplied in the pre-market notification provides reasonable assurance that LIGAND PLUS CONTROL is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 16 2004

Ms. Candice Betz
Quality Manager
Consolidated Technologies, Inc.
4401 Freidrich Lane
Building 1, Suite 100
Austin, TX 78744

Re: k033344
Trade/Device Name: Ligand Plus Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: December 17, 2003
Received: December 18, 2003

Dear Ms. Betz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS OF USE STATEMENT

510(k) number (if known): K 033344

Device name:

LIGAND PLUS CONTROL

Indications for use:

LIGAND PLUS CONTROL, Levels 1, 2 and 3, is a lyophilized human serum based assayed quality control material intended to monitor the performance of clinical immunoassay test procedures that analyze immunochemistries and therapeutic drugs as listed in this package insert.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033344

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use ____